Walgreens

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Policy title:	**Good Faith Dispensing of Controlled Substances**
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Version:	**1.0**
Owner:	**Vice President, Pharmacy Quality, Compliance, and Patient Safety**
Description:	**This policy describes the elements of Good Faith Dispensing in conjunction with state and federal requirements.**

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DEFENDANT EXHIBIT

WAG-MDL-02626

1. Purpose

This policy sets forth the requirements and processes for Good Faith Dispensing to ensure controlled substances are dispensed in alignment with all relevant laws and regulations.

2. Scope

This policy applies to all Walgreens Pharmacy Team Members in the U.S., Puerto Rico, the U.S. Virgin Islands, and all other U.S. territories.

3. Definitions

The following terms are used in this policy:

Term	Meaning
Corresponding Responsibility Documentation	Documentation that indicates a controlled substance prescription was issued for a legitimate medical purpose in the usual course of professional practice.
Good Faith Dispensing ("GFD")	The evaluation of a controlled substance prescription by a pharmacist prior to dispensing, using his/her professional judgment, to confirm that the prescription is valid and issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
Pharmacy Team Member	Pharmacists, Pharmacy Technicians, Pharmacy Interns or any other individual who is permitted to work in the pharmacy.
Prescription Drug Monitoring Program	An electronic database that tracks controlled substance prescription dispensing.
Red Flags	Warning signs that may indicate a controlled substance prescription was not issued for a legitimate medical purpose in the usual course of professional practice.

4. Policy

4.1 General Requirements

1) The pharmacist must use professional judgment in conjunction with state and federal controlled substance laws when dispensing all prescriptions.
2) A prescription for a controlled substance, to be valid, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
3) Pharmacists have a corresponding responsibility in ensuring all controlled substances prescriptions are filled for a legitimate medical purpose.
4) Timing must be evaluated as part of the GFD review to determine appropriateness of dispensing at the current time. If a prescription is refused due to timing concerns, it may be dispensed at a later, more appropriate date.
5) For Hospice and oncology patients only: In the instance a pharmacist is unable to reach the prescriber's clinical staff, the pharmacist must document all steps that were taken prior to making the decision to approve dispensing.
6) Any pharmacist who fails to comply with any requirement in this policy is subject to disciplinary action up to and including termination of employment.

4.2 Red Flags and Corresponding Responsibility Documentation

1) Prior to dispensing, pharmacists must review the relevant information and decide whether the prescription meets the elements of Good Faith Dispensing. At a minimum, this means that any identified Red Flags have been resolved. However, the absence of Red Flags may not be sufficient justification for dispensing a controlled substance.
2) If Red Flags are identified and resolved, the pharmacist must document resolution of those Red Flags, either by writing on the prescription prior to scanning, annotating on the image, or on the Good Faith Dispensing Worksheet. If Red Flags are identified and cannot be resolved, then the prescription must not be dispensed.
3) In addition, the pharmacist should identify and document evidence that supports the determination that the prescription was issued for a legitimate medical purpose. This is known as Corresponding Responsibility Documentation.
4) Thorough, appropriate and unambiguous documentation of the pharmacists' GFD review process, including recording the resolution of Red Flags and evidence that

supports the legitimacy of the prescription, demonstrates adherence to corresponding responsibility requirements and this policy.

4.3 Team Member Roles and Responsibilities

1) Every Pharmacy Team Member has a role in ensuring that the elements of Good Faith Dispensing are met.
2) The pharmacist performing product review or completing an electronic Good Faith Dispensing worksheet is responsible for ensuring that the elements of Good Faith Dispensing have been met.

5. Good Faith Dispensing Requirements for Controlled Substances

5.1 Identify

When performing a GFD evaluation, pharmacists must identify any Red Flags. While some Red Flags have been provided in this section of the policy as guidance, pharmacists should use their professional judgment, experience, and trends to identify additional Red Flags.

Note: Pharmacists must follow state law with regard to obtaining identification prior to dispensing a controlled substance prescription. If at any time a pharmacist is in doubt as to the legitimacy of a prescription or if the patient is unknown to the pharmacist, the pharmacist must require proper identification.

1) Usual Course of Professional Practice:
    i. Pharmacists must determine if the controlled substance prescription is written outside the usual course of the prescriber's professional practice or specialization.
    ii. Pharmacist must determine if there are unusual geographical distances between the patient, pharmacist and/or prescriber that cannot be reasonably explained. The pharmacist must feel comfortable that the explanation is reasonable and may confirm with the patient or prescriber as needed.
    iii. Does the prescription appear to be issued pursuant to an online diagnosis questionnaire? For example, does the prescriber only list a website on the prescription which indicates that he/she has no physical office where patients can be examined?

iv. Is there therapeutic duplication of two or more long-acting and/or two or more short acting medications?

2) Prescriptions:

i. Unusual dosages, directions, or quantities beyond those normally prescribed.

ii. Dosages or directions that conflict with approved labeling.

iii. Frequent combination prescriptions for known drug "cocktails" such as a benzodiazepine, opioid and muscle relaxer or combination of an opioid, benzodiazepine and stimulant (e.g., amphetamine/dextroamphetamine).

iv. Increased frequency of prescriptions for the same or similar controlled substances.

v. The physical appearance of the prescription appears to be altered, forged or contain misspellings.

vi. The prescription contains atypical terms or abbreviations, or none at all.

vii. The prescription has an unusual presentation – prescriber's handwriting is too legible, is written in different color inks, different handwriting or with erasure marks.

viii. The prescription is being filled early without an explanation, or there is a pattern of early refills.

ix. Extended or unexplained use of cough syrups.

x. Continuous prescriptions for immediate release rather than long acting formulations.

xi. The prescription was refused by another pharmacy or pharmacist.

xii. The prescription is written for a large quantity for a minor, acute or self-limiting condition.

3) Patients:

i. Patient consistently requests early refills.

ii. Patient exhibits "drug seeking" type behaviors (e.g., manipulative, demanding behavior to obtain medication).

iii. Patient travels long distances that cannot be reasonably explained.

iv. Patient remains on the same therapy for an extended period of time.

v. Patient selectively fills only controlled substance prescriptions.

vi. Patient requests to pay by cash (i.e., no third party billing) or by using a cash discount card (in a possible attempt to circumvent third party billing restrictions).

vii. Patient has controlled substance prescriptions from several different prescribers.

viii. Patient has controlled substance prescriptions from several different pharmacies.

ix. Patient is unable to provide a valid reason for taking the controlled substance (i.e., a valid diagnosis or legitimate medical purpose).

x. Multiple patients drop off prescriptions around the same time for the same medication from the same prescriber.

xi. Individual is picking up controlled substance prescriptions on behalf of multiple patients. The individuals reside at different addresses or have no apparent relationship to each other.

xii. Patients at the same address on the same or similar controlled substance medications from the same prescriber.

xiii. Individual presents with a chronic prescription as a new patient that has not been previously been filled by the pharmacy.

4) Prescribers:

i. Prescriber is unwilling to provide the reason for prescribing the controlled substance in order for the pharmacist to confirm that it is for a legitimate medical purpose.

ii. Prescriber is unwilling to partner with the pharmacist and provide necessary documentation such as diagnosis, previous therapies, expected length of therapy, etc.

iii. Prescriber is always difficult to reach or only willing to communicate through office staff.

iv. Prescriber is abusive or threatening.

v. Prescriber is writing prescriptions for him or herself, partner or family members.

vi. Prescriber is writing for a large amount of amphetamine prescriptions for adults.

vii. Prescriber consistently writes prescriptions for the same controlled substances and doses for different patients (e.g., lack of individualized therapy).

viii. Prescriber frequently authorizes early refills without explanation or documentation.

ix. Prescriber operates as a cash only business and does not accept government or other third party insurance.

x. Prescriber has a different phone number on the prescription than the phone number found using the "prescriber inquiry" function in Intercom Plus.

5.2 Validate

1) Pharmacists must contact a prescriber's office if, despite trying other validation requirements, they are unable to resolve Red Flags related to the prescription to determine if it is appropriate to dispense the controlled substance prescription. Validation may include, but not be limited to, taking the following actions:

    i. Verification that the patient is under the care of the prescriber on the prescription.

    ii. Verification that the patient has, in fact, been prescribed a controlled substance.

    iii. Obtaining information to support a patient travelling a long distance to have a controlled substance prescription filled.

    iv. Obtaining a clinical diagnosis to support a prescription for chronic opioid use.

    v. If the prescriber's clinical staff is unable to provide the information necessary to validate a prescription, speak with the prescriber about the remaining issues with the prescription.

        i. Routine calls to the prescriber to validate prescriptions are not required under this policy.

vi. Confirm that the prescriber has authority to prescribe controlled substances by verifying the validity of the prescriber's information including the DEA number and state license number.

i. StoreNet > Rx Ops > Pharmacy Policy and Procedures > Rx Integrity >DEA >DEA License Number Validation

vii. **Prescription Drug Monitoring Program (PDMP)**: Follow State Specific Information to determine if additional PDMP information is required to confirm the appropriateness of the prescription.

2) **Evaluate the Elements of Good Faith Dispensing**: If the pharmacist cannot resolve a Red Flag without additional information from the prescriber's clinical staff and they cannot be reached, do not dispense the prescription. Even if the prescriber's clinical staff verifies that the prescription is valid, pharmacists have a responsibility to confirm and document that the elements of Good Faith Dispensing are satisfied prior to dispensing.

5.3 Document

Pharmacists must document all efforts used to validate good faith dispensing on the GFD Worksheet, in IC+ prescription annotations, or on the hard copy prior to scanning.

1) **Prescriber information**: If the prescriber's clinical staff confirms the validity of the prescription, document the date, name of the individual spoken to and any other pertinent information such as diagnosis, treatment tried and failed, length of treatment, plan to taper, diagnostic tests, etc.

2) **Patient information**: If the patient provides an ID or other pertinent information such as medical history, health conditions, allergies, previous therapy, etc., document the information as appropriate.

3) **Elements of Good Faith**: Document any information pertaining to the elements of good faith dispensing on the GFD Review Worksheet, prescription image or hard copy. If in the pharmacist's professional judgement, he or she determines the prescription is valid and issued for a legitimate medical purpose, then the pharmacist must document resolution of all Red Flags identified, including conversations held with the patient and/or prescriber. Inclusion of Corresponding Responsibility Documentation provides additional support that the pharmacist has performed due diligence prior to dispensing.

5.4 Pharmacist Right to Refuse

1) Pharmacists must refuse to dispense a controlled substance prescription if he/she determines the elements of GFD are not met.
2) Pharmacists must inform the patient that they are unable to fill the prescription using the following refusal language:
    i. "Based on my clinical review and professional judgment, this prescription does not meet requirements that warrant dispensing. Therefore, we cannot fill this prescription in good faith. I apologize for any inconvenience."
    ii. Dispensing a prescription that the pharmacist knows is fraudulent is a violation of state and federal regulations.
        i. If asked by law enforcement to dispense a fraudulent prescription, do not dispense and inform law enforcement that this is a violation of state and federal regulations.
        ii. Knowingly dispensing a prescription with anything other than what is written on the prescription (i.e., candy, OTC medication, etc.) is a violation of company policy.
3) Refer to and comply with Walgreens State-Specific Pharmacy Reference Guide documents for any additional dispensing and/or reporting requirements associated with controlled substances.

6. Related Policies & Documents

1) Dispensing Prescription Products Policy
2) Electronic Good Faith Dispensing (EGFD) Job Aid
3) Electronic Good Faith Dispensing FAQs
4) Electronic Good Faith Dispensing Talking Points
5) Morphine Milligram Equivalent (MME) Calculation
6) CDC MME Handout
7) Opioid Dosage Calculator

7. Policy Revision History

Version number	Issue date	Description of changes
Version 1.0	29 February 2020	Main changes comprise: • Target Drug Good Faith Dispensing Policy and Good Faith Dispensing Policies are consolidated into one document in the new policy format.

8. Contact information

For any questions on this policy, utilize Ask the Retail Hub: Pharmacy > Prescription Fill Process/ Prescription Intake > Good Faith Dispensing

9. Approval Matrix

Name	Title
Tasha Polster	Vice President, Pharmacy Quality, Compliance, and Patient Safety